K053505 1/2

BIOMET

AUG 14 2006

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Tracy Bickel Johnson, RAC

Proprietary Name: Regenerex™ Ultra Porous Construct- Titanium Knee Augments

Common Name: Knee Augments

Classification Name: -prosthesis, knee, patello/femorotibial, semi-constrained, cemented, polymer/metal/polymer (888.3560)
-prosthesis, knee, patello/femorotibial, semi-constrained, uncemented, porous, coated, polymer/metal/polymer (888.3565)
-prosthesis, knee, femorotibial, constrained, cemented, metal/polymer (888.3510)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Maxim® Accel Knee System- K023546 (Biomet, Inc.); MCK Knee System- K915132 (Biomet, Inc.); Trabecular Metal Knee System Augments- K040487 (Zimmer Holdings); NexGen Complete Knee Solution Trabecular Metal- K024161 (Zimmer Holdings); Oncology Salvage System- K002757 (Biomet, Inc.)

Device Description: The Regenerex™ Ultra Porous Construct- Titanium Knee Augments are designed for attachment to selected commercially available Biomet® tibial base plates and femoral components using bolts, cement or a combination of both (depending on the augment).

The augments are manufactured to interface with selected femoral and tibial Biomet® components. The femoral augments come in nine (9) different sizes that correspond with the sizes of the femoral components. The thickness options for the femoral augments vary from 5mm to 15mm. The tibial augments are available in 10° wedge and block form. The block augments are available in three (3) thicknesses for nine (9) tibial sizes. The OSS femoral augments are available in a 3.5mm thick anterior flange augment. The OSS tibial augments are available in monoblock and block form. The monoblocks are only available in 10mm thicknesses for three tibial sizes, while the block augments are available in 10mm and 20 mm sizes for three tibial sizes.

Intended Use:
Femoral and Tibial Augments are intended for:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

Cemented and uncemented applications

The Regenerex™ femoral augments are indicated for use with the Vanguard™ Total Knee System.

The Regenerex™ tibial augments are indicated for use with standard and offset Biomet® Tibial Trays.

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510(k) Summary
Biomet Manufacturing Corp.
Regenerex™ Ultra Porous Construct- Titanium Knee Augments

The OSS Augments are intended for:

1. Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis, or traumatic arthritis
2. Correction of varus, valgus, or posttraumatic deformity
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement
4. Ligament deficiencies
5. Tumor Resection
6. Revision of previously failed total joint arthroplasty
7. Trauma

These are single use implants
These devices are for cemented use only

Summary of Technologies: The technological characteristics (material modification, design, sizing, indications) of the Regenerex™ Ultra Porous Construct- Titanium Knee Augments are similar to or identical to the predicate devices.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet Manufacturing, Inc
% Ms. Tracy Bickel Johnson, RAC
Manager, Regulatory Affairs
P.O. Box 587
Warsaw, Indiana 46581-0587

AUG 14 2006

Re: K053505
Trade/Device Name: Regenerex™ Ultra Porous Construct – Titanium OSS Knee Augments
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, KRO, JWH
Dated: May 15, 2006
Received: May 16, 2006

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k)

premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K053505 (1)/2

Indications for Use

510(k) Number (if known):

Device Name: Regenerex™ Ultra Porous Construct- Femoral and Tibial Knee Augments

Indications For Use:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

Cemented and uncemented applications

The Regenerex™ femoral augments are indicated for use with the Vanguard™ Total Knee System.

The Regenerex™ tibial augments are indicated for use with standard and offset Biomet® Tibial Trays.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use__NO____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buch MD for ODE

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053505

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Indications for Use

510(k) Number (if known):

Device Name: Regenerex™ Ultra Porous Construct- Titanium OSS Knee Augments

Indications For Use:

1. Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis, or traumatic arthritis
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement
4. Ligament deficiencies
5. Tumor Resection
6. Revision of previously failed total joint arthroplasty
7. Trauma

These are single use implants
These devices are for cemented use only

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brecht M.D.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053505